

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization  
International Bureau



(43) International Publication Date  
29 November 2001 (29.11.2001)

PCT

(10) International Publication Number  
**WO 01/91025 A1**

(51) International Patent Classification<sup>7</sup>: **G06F 19/00**

(21) International Application Number: **PCT/GB01/02252**

(22) International Filing Date: **21 May 2001 (21.05.2001)**

(25) Filing Language: **English**

(26) Publication Language: **English**

(30) Priority Data:  
**0012840.5 25 May 2000 (25.05.2000) GB**

(71) Applicant (for all designated States except US): **THIRD-PHASE LIMITED [GB/GB]; 292 Cambridge Science Park, Milton Road, Cambridge CB4 1LH (GB).**

(72) Inventors; and

(75) Inventors/Applicants (for US only): **CORBETT-CLARK, Timothy, Alexander [GB/GB]; Ivy Cottage,**

Queen Street, Cowlinge, Newmarket, Suffolk CB8 9QB (GB). **HOLT, Mark, Rowan, Gorton [AU/GB]; 37 Holbrook Road, Cambridge, Cambridgeshire CB1 7SX (GB).**

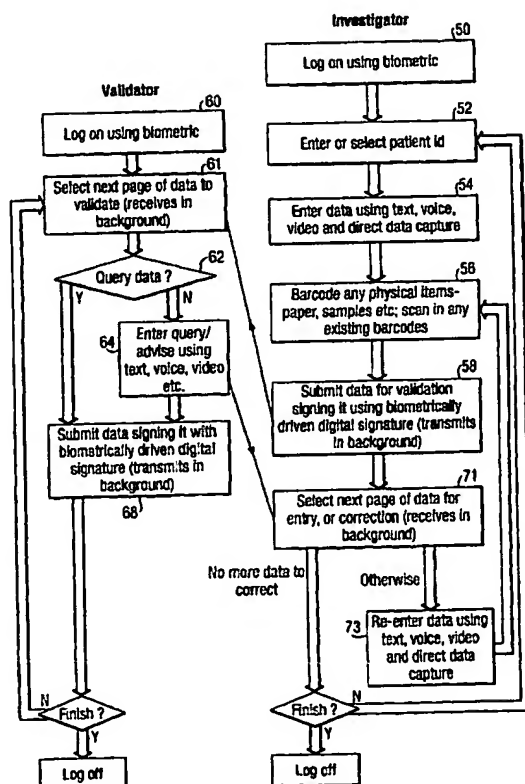
(74) Agents: **NICHOLLS, Michael, John et al.; J.A. Kemp & Co., Gray's Inn, 14 South Square, London WC1R 5JJ (GB).**

(81) Designated States (national): **AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.**

(84) Designated States (regional): **ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).**

[Continued on next page]

(54) Title: **METHOD AND SYSTEM FOR COLLECTION AND VERIFICATION OF DATA FROM PLURAL SITES**



(57) Abstract: A system for providing secure and accurate acquisition of data, such as clinical trials data, from a plurality of sites comprises a plurality of mobile user stations and a plurality of validator stations which intercommunicate. The user stations include a mobile computer, communication links, interface to local medical devices to provide for capture of medical data and bar code printers for recording physical items and provide for user to fill an electronic case record form (CRF). When complete the form is digitally signed by a signature derived from a biometric authentication of the user and is submitted for immediate validation by the validator. The validator can either validate and sign off the form using a biometrically driven digital signature or can request correction of certain part of the form. Both the final form and any earlier version of it are stored in a secured database. The electronic case record forms are encoded in XML, with any arbitrary binary data encoded in Radix64. For digital signing of the forms the XML documents are normalized by removing contentless white spaces and converting text to Unicode before application of the digital signature algorithm. The digital signature and public key are encoded as Radix64 and appended to the XML document for transmission.

WO 01/91025 A1